REMARKS

Reconsideration of this application is requested. Claims 37-145, 148-181 and 183-190 are in the case. Claims 146, 476 and 182 have been canceled without prejudice.

I. CLAIM OBJECTIONS

The Examiner has objected that dependent claims should begin with "The" and not "A." The dependent claims have been corrected accordingly.

II. THE 35 U.S.C. 112, REJECTIONS

Claims 37-186 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors at the time the application was filed had possession of the claimed invention. In particular, objection is made that the claims broadly claim a "substrate." Claims 37-186 are also rejected under 35 U.S.C. 112, first paragraph, on the ground that the specification while being enabling for the specification examples at pages 20-28 allegedly does not reasonably provide enablement for the broad scope of the claims. Those rejections are respectfully traversed.

The Examiner asserts that the specification gives little direction as to what

the substrate is, only quoting a tablet core and conveyor belt as examples. However, the term "substrate" is well known and understood in the field of coating of pharmaceuticals. Moreover, as well as a tablet core and a conveyor belt, the specification also discloses that the substrate may be:

- a sheet comprising plastics material, for example low-adhesion plastics material (page 3 lines 35-37);
- an edible film which can be administered orally (page 16 line 4);
- a base layer which is removable from the substrate (it could, for example be an edible film) (page 24 lines 5-6);
- a tape, which may be inedible and therefore removed, or may be edible, or may be used as a patch (page 29 lines 24-35).

As noted by the Examiner, the substrate can also be a part of the coating apparatus , or a tablet core. There is, further, a general discussion of pharmaceutical substrates on page 1 lines 5-28.

The Examiner has asserted that only two types of coating are disclosed, powder and liquid. However, one of ordinary skill in this art would readily understand that the invention is not limited to those two embodiments, and would have no difficulty in carrying out the invention in the scope as claimed. The applicants would be prepared, if absolutely necessary, to limit the claims to the application of the active coating material as powder or liquid. As to the application of a cover coating on top of the active layer (as specified, for example, in claim 148), this could be applied, for example, electrostatically (page 6, lines

30-31). Electrostatic application of a coating to a pharmaceutical core is disclosed in WO 92/14451, of record in the present case. The cover coating material may be in the form of a powder (page 6, lines 31-32) or may be in the form of a liquid (for example, page 6, lines 17-18). A cover coating may also be applied, for example as a preformed sheet or film (page 7, lines 35-36). Such application and other methods of coating an existing pharmaceutical product are well known to persons of ordinary skill in this art.

Othe application of a cover coating to an existing pharmaceutical product is well known to persons of ordinary skill, and hardly requires explanation.

The Examiner asserts that only a few examples of the components of the coating layers or covers are disclosed. This objection is respectfully traversed. As well as the specific examples on page 21ff, relevant additional disclosures appear as follows:

- the active material is discussed on page 1 lines 29-35;
- excipients are mentioned on page 5 lines 1-7, page 19 lines 31-37, page 20 lines 19-25;
- contents of liquid coating materials are discussed on page 23 lines 29-35.

The specification clearly provides an enabling disclosure with regard to coating layers.

The Examiner further asserts that the specification gives little direction as to what substrates or compounds are susceptible to having an electrostatic

charge so as to be suitable for the claimed invention. However, substrates and materials for this purpose are well known. For example, electrostatic coating of powder material onto pharmaceutical substrates is known from WO 92/14451 and the corresponding U.S. Patents 5,470,603 and 5,656,080, and from US Patent 6,177,479 and electrostatic coating of biologically active material is also already known from WO 96/35413. Thus, a person skilled in the art would have no difficulty in making an active coating material for use in the invention and would have no difficulty in using it (i.e., in applying it to a substrate). It is noted that WO 96/35413 gives a test for whether or not a powder material is susceptible to movement under the action of electrostatic forces (see page 12 lines 3-28.)

Withdrawal of the outstanding 35 U.S.C. 112, first paragraph, rejections is believed to be in order. Such action is respectfully requested.

A number of claims stand rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite in that these rejected claims contain the term "such that." The Examiner has suggested the alternative expression "wherein." In light of that indication, the claims have been amended where appropriate to effect the corrections suggested by the Examiner.

Withdrawal of the outstanding 35 U.S.C. 112, second paragraph, rejection is now believed to be in order. Such action is respectfully requested.

III. THE PRIOR ART REJECTIONS

Claims 98, 113, 114, 115, 116 and 166 stand rejected under 35 U.S.C. 102(b) as allegedly anticipated by or, in the alternative, rejected under 35 U.S.C. 103(a) as allegedly obvious in view of U.S. Patent No. 4,925,670 to Schmidt. Claims 98, 100, 101, 103-109, 113-116, 146, 147, 154, 166 and 181 stand rejected under rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Schmidt. Those rejections are respectfully traversed.

In order to reduce the issues, Claims 146 and 147 have been canceled without prejudice. Claim 181 has been amended to incorporate Claim 182, and Claim 182 has been canceled without prejudice. The remaining rejected claims (Claims 98, 100, 101, 103-109, 113-116, 154, 166 and 181) are not anticipated or rendered obvious by Schmidt.

Schmidt relates to a drug dosage form comprising a film-like carrier material coated with an active agent-containing coating. The active agent-containing coating is divided into dosage units, each unit being individually removable from the carrier material. Schmidt has no disclosure of using the coating apparatus as the substrate, as required by the rejected claims. The carriers used in Schmidt are papers, plastic films or sheets and thin metal foils (column 2, line 61 following). As mentioned by Schmidt (column 5, lines 4-23), sub-division of the active material and backing layer can be carried out at the manufacturers, but Schmidt contains no disclosure of removal of the active

material from the backing layer by the manufacturer, in contrast to the process specified in the rejected claims. Indeed, as mentioned above, Schmidt is concerned with providing printed information concerning the active agent. Column 2, lines 45-49 mentions that the carrier can be printed with various information and column 3, lines 6-24 also mentions the possibility of printing the name, details concerning the constituents and dosage information on the carrier, as well as the need for a label during shipping and handling. Clearly, the possibility of providing such information on the carrier is removed if the active layer is removed from the carrier (the coating apparatus) in the manufacturing process.

Schmidt also states (column 3, lines 16-24) that, in the case of drugs which have to be taken regularly, the complete administration plan can be provided in such a way that a simple ingestion check is ensured. Schmidt states that as the individual dosage units are removed from the carrier, the carrier remains in existence, so that none of the printed information is lost. Again, such advantages of Schmidt would no longer apply if the substrate is the coating apparatus, because the substrate would be removed, not by the hospital or pharmacist or by the patient, but by the manufacturer.

Withdrawal of the outstanding anticipation/obviousness rejections based on Schmidt is now believed to be in order. Such action is respectfully requested.

IV. NEW CLAIMS

New product claims 187-190 are presented which refer to the coating on the substrate. They are based on Claims 171, 179, 181 and 184 (without reference to electrostatic deposition of powder) and recite the substrate as the conveyor belt. No new matter is entered.

Allowance of the application is awaited.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CHANGES MADE

IN THE CLAIMS

37. (Amended). [A] The method of coating a substrate, the method comprising the step of applying an active coating material to the substrate to form an active coating layer, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate, and wherein the active coating material is applied electrostatically as a powder.

38. (Amended). [A] The method according to claim 37, which further includes the step of removing the active coating layer from the substrate.

39. (Amended). [A] The method according to claim 37, wherein the substrate is pre-coated with one or more coating layers removable from the substrate and the active coating layer is removable therewith.

40. (Amended). [A] The method according to claim 37, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is substantially completely covered by the cover coating layer, and [such that] wherein the cover coating layer is removable from the substrate.

41. (Amended). [A] The method according to claim 40, wherein the

cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

42. (Amended). [A] The method according to claim 40, wherein the cover coating layer is removable with the active coating layer.

43. (Amended). [A] The method according to claim 40, wherein the cover material includes biologically active material.

44. (Amended). [A] The method according to claim 40, wherein the method further includes the step of applying a further coating material to a surface of the substrate to form a further coating layer [such that] wherein the further coating layer is removable from the substrate.

45. (Amended). [A] The method according to claim 44, wherein the further coating material includes biologically active material, the further coating layer forming a further active coating layer and the method further includes the step of applying a further cover coating material onto the further active coating layer to form a further cover coating layer [such that] wherein the further active coating layer is substantially completely covered by the further cover coating layer and [such that] wherein the further cover coating layer is removable from the substrate.

46. (Amended). [A] The method according to claim 45, wherein the active material of the active coating layer and the further active coating layer are the same.

47. (Amended). [A] The method according to claim 40, wherein the method includes the step of applying a second active coating layer onto a surface of the substrate, the second active coating layer forming a second active coating region on the surface of the substrate, the second active coating layer being removable from the substrate, and applying a second cover coating layer onto the second active coating layer to form a second cover coating layer [such that] wherein the second active coating layer is substantially completely covered by the second cover coating layer, the second cover coating layer being substantially separate from the first cover coating layer, and being removable from the substrate.

48. (Amended). [A] The method according to claim 37 which comprises applying to the substrate a base coating layer, applying the active material to the base layer and applying a cover coating layer over the active coating layer, the three layers being removable together by peeling from the substrate in the form of a three-layer wafer.

49. (Amended). [A] The method according to claim 48, wherein the base coating layer and the cover coating layer are each applied electrostatically as a powder and each fused to form a film.

50. (Amended). [A] The method according to claim 37 wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

51. (Amended). [A] The method according to claim 37 wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

52. (Amended). [A] The method according to claim 37 wherein the method comprises supporting the substrate adjacent to the source of the active coating material with a surface of the substrate maintained at such a different electric potential from that of the active coating material that the application of the electric potential causes the active coating material to move from the source of the active coating material towards the substrate, a surface of the substrate becoming coated with the active coating material.

53. (Amended). [A] The method according to claim 37 wherein the substrate is supported from above and the powder moves from the source

upwards towards a lower surface of the substrate.

54. (Amended). [A] The method according to claim 37 wherein the quantity of active material in the active coating applied to the substrate is substantially equal to one dose of the active material.

55. (Amended). [A] The method according to claim 37 wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

57. (Amended). [A] The method according to claim 56, which further includes the step of removing the active coating layer from the substrate.

58. (Amended). [A] The method according to claim 56, wherein the substrate is pre-coated with one or more coating layers removable from the substrate and the active coating layer is removable therewith.

59. (Amended). [A] The method according to claim 56, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is substantially completely covered by the cover coating layer, and [such that] wherein that cover coating layer is removable from the substrate.

60. (Amended). [A] The method according to claim 59, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

61. (Amended). [A] The method according to claim 59, wherein the cover coating layer is removable with the active coating layer.

62. (Amended). [A] The method according to claim 59, wherein the cover material includes biologically active material.

63. (Amended). [A] The method according to claim 59, wherein the method further includes the step of applying a further coating material to a surface of the substrate to form a further coating layer [such that] wherein the further coating layer is removable from the substrate.

64. (Amended). [A] The method according to claim 63, wherein the further coating material includes biologically active material, the further coating layer forming a further active coating layer and the method further includes the step of applying a further cover coating material onto the further active coating layer to form a further cover coating layer [such that] wherein the further active coating layer is substantially completely covered by the further cover coating

layer and [such that] wherein the further cover coating layer is removable from the substrate.

65. (Amended). [A] The method according to claim 64, wherein the active material of the active coating layer and the further active coating layer are the same.

66. (Amended). [A] The method according to claim 59, wherein the method includes the step of applying a second active coating layer onto a surface of the substrate, the second active coating layer forming a second active coating region on the surface of the substrate, the second active coating layer being removable from the substrate, and applying a second cover coating layer onto the second active coating layer to form a second cover coating layer [such that] wherein the second active coating layer is substantially completely covered by the second cover coating layer, the second cover coating layer being substantially separate from the first cover coating layer, and being removable from the substrate.

67. (Amended). [A] The method according to claim 56, which comprises applying to the substrate a base coating layer, applying the active material to the base layer and applying a cover coating layer over the active coating layer, the three layers being removable together by peeling from the substrate in the form

of a three-layer wafer.

68. (Amended). [A] The method according to claim 67, wherein the base coating layer and the cover coating layer are each applied electrostatically as a powder and each fused to form a film.

69. (Amended). [A] The method according to claim 56, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

70. (Amended). [A] The method according to claim 56, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

71. (Amended). [A] The method according to claim 56, wherein the method comprises supporting the substrate adjacent to source of the active coating material with a surface of the substrate maintained at such a different electric potential from that of the active coating material that the application of the electric potential causes the active coating material to move from the source of the active coating material towards the substrate, a surface of the substrate becoming coated with the active coating material.

72. (Amended). [A] The method according to claim 56, wherein the substrate is supported from above and the powder moves from the source upwards towards a lower surface of the substrate.

73. (Amended). [A] The method according to claim 56, wherein the, quantity of active material in the active coating applied to the substrate is substantially equal to one dose of the active material.

74. (Amended). [A] The method according to claim 56, wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

76. (Amended). [A] The method according to claim 75, which further includes the step of removing the active coating layer from the substrate.

77. (Amended). [A] The method according to claim 75, wherein the substrate is pre-coated with one or more coating layers removable from the substrate and the active coating layer is removable therewith.

78. (Amended). [A] The method according to claim 75, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is

substantially completely covered by the cover coating layer, and [such that] wherein that cover coating layer is removable from the substrate.

79. (Amended). [A] The method according to claim 78, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

80. (Amended). [A] The method according to claim 78, wherein the cover coating layer is removable with the active coating layer.

81. (Amended). [A] The method according to claim 78, wherein the cover material includes biologically active material.

82. (Amended). [A] The method according to claim 78, wherein the method further includes the step of applying a further coating material to a surface of the substrate to form a further coating layer [such that] wherein the further coating layer is removable from the substrate.

83. (Amended). [A] The method according to claim 82, wherein the further coating material includes biologically active material, the further coating layer forming a further active coating layer and the method further includes the step of applying a further cover coating material onto the further active coating

layer to form a further cover coating layer [such that] wherein the further active coating layer is substantially completely covered by the further cover coating layer and [such that] wherein the further cover coating layer is removable from the substrate.

84. (Amended). [A] The method according to claim 83, wherein the active material of the active coating layer and the further active coating layer are the same.

85. (Amended). [A] The method according to claim 78, wherein the method includes the step of applying a second active coating layer onto a surface of the substrate, the second active coating layer forming a second active coating region on the surface of the substrate, the second active coating layer being removable from the substrate, and applying a second cover coating layer onto the second active coating layer to form a second cover coating layer [such that] wherein the second active coating layer is substantially completely covered by the second cover coating layer, the second cover coating layer being substantially separate from the first cover coating layer, and being removable from the substrate.

86. (Amended). [A] The method according to claim 75, which comprises applying to the substrate a base coating layer, applying the active material to the

base layer and applying a cover coating layer over the active coating layer, the three layers being removable together by peeling from the substrate in the form of a three-layer wafer.

87. (Amended). [A] The method according to claim 86, wherein the base coating layer and the cover coating layer are each applied electrostatically as a powder and each fused to form a film.

88. (Amended). [A] The method according to claim 75, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

89. (Amended). [A] The method according to claim 75, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

90. (Amended). [A] The method according to claim 75, wherein the method comprises supporting the substrate adjacent to source of the active coating material with a surface of the substrate maintained at such a different electric potential from that of the active coating material that the application of the electric potential causes the active coating material to move from the source of the active coating material towards the substrate, a surface of the substrate

becoming coated with the active coating material.

91. (Amended). [A] The method according to claim 75, wherein the substrate is supported from above and the powder moves from the source upwards towards a lower surface of the substrate.

92. (Amended). [A] The method according to claim 75, wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

94. (Amended). [A] The method according to claim 93, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is substantially completely covered by the cover coating layer, and [such that] wherein that cover coating layer is removable from the substrate, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

95. (Amended). [A] The method according to claim 93, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

96. (Amended). [A] The method according to claim 93, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

97. (Amended). [A] The method according to claim 93 wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

98 (Amended). A method of coating a substrate using a coating apparatus, the method including the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating is removed as a wafer.

99. (Amended). [A] The method according to claim 98 wherein the active material is applied to a conveyor belt.

100. (Amended). [A] The method according to claim 98, wherein the substrate is pre-coated with one or more coating layers removable from the substrate and the active coating layer is removable therewith.

101. (Amended). [A] The method according to claim 98, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is substantially completely covered by the cover coating layer, and [such that] wherein that cover coating layer is removable from the substrate.

102. (Amended). [A] The method according to claim 101, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

103. (Amended). [A] The method according to claim 101, wherein the cover coating layer is removable with the active coating layer.

104. (Amended). [A] The method according to claim 101, wherein the cover material includes biologically active material

105. (Amended). [A] The method according to claim 101, wherein the method further includes the step of applying a further coating material to a surface of the substrate to form a further coating layer [such that] wherein the further coating layer is removable from the substrate.

106. (Amended). [A] The method according to claim 105, wherein the further coating material includes biologically active material, the further coating layer forming a further active coating layer and the method further includes the step of applying a further cover coating material onto the further active coating layer to form a further cover coating layer [such that] wherein the further active coating layer is substantially completely covered by the further cover coating layer and [such that] wherein the further cover coating layer is removable from the substrate.

107. (Amended). [A] The method according to claim 106, wherein the active material of the active coating layer and the further active coating layer are the same.

108. (Amended). [A] The method according to claim 101, wherein the method includes the step of applying a second active coating layer onto a surface of the substrate, the second active coating layer forming a second active coating region on the surface of the substrate, the second active coating layer being removable from the substrate, and applying a second cover coating layer onto the second active coating layer to form a second cover coating layer [such that] wherein the second active coating layer is substantially completely covered by the second cover coating layer, the second cover coating layer being substantially separate from the first cover coating layer, and being removable from the

substrate.

109. (Amended). [A] The method according to claim 98, which comprises applying to the substrate a base coating layer, applying the active material to the base layer and applying a cover coating layer over the active coating layer, the three layers being removable together by peeling from the substrate in the form of a three-layer wafer.

110. (Amended). [A] The method according to claim 109, wherein the base coating layer and the cover coating layer are each applied electrostatically as a powder and each fused to form a film.

111. (Amended). [A] The method according to claim 98, wherein the method comprises supporting the substrate adjacent to source of the active coating material with a surface of the substrate maintained at such a different electric potential from that of the active coating material that the application of the electric potential causes the active coating material to move from the source of the active coating material towards the substrate, a surface of the substrate becoming coated with the active coating material.

112. (Amended). [A] The method according to claim 98, wherein the substrate is supported from above and the powder moves from the source

upwards towards a lower surface of the substrate.

113. (Amended). [A] The method according to claim 98, wherein the quantity of active material in the active coating applied to the substrate is substantially equal to one dose of the active material.

114. (Amended). [A] The method according to claim 98, wherein the wafer removed from the coated substrate is a solid dosage form.

115. (Amended). [A] The method according to claim 98, wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

116. (Amended). [A] The method according to claim 98 wherein the active coating material is applied as a liquid and after the active coating layer is applied the active coating material is treated to form an active film coating.

117. (Amended). [A] The method according to claim 116, wherein a predetermined number of droplets of active coating material are applied to the surface of the substrate.

118. (Amended). [A] The method according to claim 116, wherein an ink

jet head is used to apply coating material to the substrate.

119. (Amended). [A] The method according to claim 116, wherein the active coating material is applied in the form of individual liquid droplets of liquid directly towards a surface of the substrate.

120 (Amended). A method of coating a substrate using a coating apparatus, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate, and the active coating material is applied electrostatically as a powder, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating is removed as a wafer.

121. (Amended). [A] The method according to claim 120, wherein the active material is applied to a conveyor belt.

122. (Amended). [A] The method according to claim 120, wherein the substrate is pre-coated with one or more coating layers removable from the substrate and the active coating layer is removable therewith.

123. (Amended). [A] The method according to claim 120, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is substantially completely covered by the cover coating layer, and [such that] wherein that cover coating layer is removable from the substrate, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

124. (Amended). [A] The method according to claim 123, wherein the cover coating layer is removable with the active coating layer.

125. (Amended). [A] The method according to claim 123, wherein the cover material includes biologically active material

126. (Amended). [A] The method according to claim 123, wherein the method further includes the step of applying a further coating material to a surface of the substrate to form a further coating layer [such that] wherein the further coating layer is removable from the substrate.

127. (Amended). [A] The method according to claim 126, wherein the method includes the step of applying a second active coating layer onto a surface of the substrate, the second active coating layer forming a second active coating

region on the surface of the substrate, the second active coating layer being removable from the substrate, and applying a second cover coating layer onto the second active coating layer to form a second cover coating layer [such that] wherein the second active coating layer is substantially completely covered by the second cover coating layer, the second cover coating layer being substantially separate from the first cover coating layer, and being removable from the substrate.

128. (Amended). [A] The method according to claim 120, which comprises applying to the substrate a base coating layer, applying the active material to the base layer and applying a cover coating layer over the active coating layer, the three layers being removable together by peeling from the substrate in the form of a three-layer wafer.

129. (Amended). [A] The method according to claim 128, wherein the base coating layer and the cover coating layer are each applied electrostatically as a powder and each fused to form a film.

130. (Amended). [A] The method according to claim 120, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

131. (Amended). [A] The method according to claim 120, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

132. (Amended). [A] The method according to claim 120, wherein the quantity of active material in the active coating applied to the substrate is substantially equal to one dose of the active material.

133. (Amended). [A] The method according to claim 120, wherein the wafer removed from the coated substrate is a solid dosage form.

134. (Amended). [A] The method according to claim 120, wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

135 (Amended). A method of coating a substrate using a coating apparatus, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate, and the active coating material is applied electrostatically as a powder, and wherein after the active coating layer is applied the active coating material is

fused to form an active film coating on the surface of the substrate, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating is removed as a wafer.

136. (Amended). [A] The method according to claim 135, wherein the active material is applied to a conveyor belt.

137. (Amended). [A] The method according to claim 135, which further includes the step of applying a cover coating material onto the active coating layer to form a cover coating layer [such that] wherein the active coating layer is substantially completely covered by the cover coating layer, and [such that] wherein that cover coating layer is removable from the substrate, and wherein the cover coating material is applied electrostatically as a powder and after application is fused to form a cover film coating.

138. (Amended). [A] The method according to claim 137, wherein the method includes the step of applying a second active coating layer onto a surface of the substrate, the second active coating layer forming a second active coating region on the surface of the substrate, the second active coating layer being removable from the substrate, and applying a second cover coating layer onto the second active coating layer to form a second cover coating layer [such that] wherein the second active coating layer is substantially completely covered by the

second cover coating layer, the second cover coating layer being substantially separate from the first cover coating layer, and being removable from the substrate.

139. (Amended). [A] The method according to claim 135, which comprises applying to the substrate a base coating layer, applying the active material to the base layer and applying a cover coating layer over the active coating layer, the three layers being removable together by peeling from the substrate in the form of a three-layer wafer.

140. (Amended). [A] The method according to claim 139, wherein the base coating layer and the cover coating layer are each applied as a powder and each fused to form a film.

141. (Amended). [A] The method according to claim 135, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

142. (Amended). [A] The method according to claim 135, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

143. (Amended). [A] The method according to claim 135, wherein the quantity of active material in the active coating applied to the substrate is substantially equal to one dose of the active material.

144. (Amended). [A] The method according to claim 135, wherein the wafer removed from the coated substrate is a solid dosage form.

145. (Amended). [A] The method according to claim 135 wherein the active coating material is applied to a plurality of individual regions on the surface of the substrate.

148. (Amended). A method of coating a plurality of coating regions onto the surface of a substrate, the method comprising the steps of:

(a) applying an active coating material to a surface of the substrate to form a plurality of active coating regions on the surface comprising active coating layers, the active coating material comprising biologically active material and being applied electrostatically as a powder,

(b) applying a cover coating material to a surface of the substrate to form a plurality of cover coating regions, the cover coating regions forming layers of cover coating material, each active coating region being substantially completely

covered by a cover coating region, [such that] wherein each region of active coating and cover coating is removable from the surface of the substrate.

149. (Amended). [A] The method according to claim 148, wherein after the active coating material is applied the active coating material is fused to form regions of active film coating on the surface of the substrate.

150. (Amended). [A] The method according to claim 148, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form regions of cover film coating.

151. (Amended). [A] The method according to claim 148, the method including the step of removing the active coating regions from the substrate to form wafers comprising active material.

152. (Amended). [A] The method according to claim 148, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

153. (Amended). [A] The method according to claim 148, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

154. (Amended). A method of coating a plurality of coating regions onto the surface of a substrate using a coating apparatus, the method comprising the steps of:

(a) applying an active coating material to a surface of the substrate to form a plurality of active coating regions on the surface comprising active coating layers, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material;

(b) applying a cover coating material to a surface of the substrate to form a plurality of cover coating regions, the cover coating regions forming layers of cover coating material, each active coating region being substantially completely covered by a cover coating region, [such that] wherein each region of active coating and cover coating is removable from the surface of the substrate, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating regions are removed as wafers.

155. (Amended). [A] The method according to claim 154, wherein the active material is applied to a conveyor belt.

156. (Amended). A method of coating a plurality of coating regions onto the surface of a substrate using a coating apparatus, the method comprising the steps of:

(a) applying an active coating material to a surface of the substrate to form a plurality of active coating regions on the surface comprising active coating layers, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material and being applied electrostatically as a powder,

(b) applying a cover coating material to a surface of the substrate to form a plurality of cover coating regions, the cover coating regions forming layers of cover coating material, each active coating region being substantially completely covered by a cover coating region, [such that] wherein each region of active coating and cover coating is removable from the surface of the substrate, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating regions are removed as wafers.

157. (Amended). [A] The method according to claim 156, wherein after the active coating material is applied the active coating material is fused to form regions of active film coating on the surface of the substrate.

158. (Amended). [A] The method according to claim 156, wherein the cover coating material is applied electrostatically as a powder and after application is fused to form regions of cover film coating.

159. (Amended). [A] The method according to claim 156, wherein the active material is applied to a conveyor belt.

160. (Amended). [A] The method according to claim 156, wherein at least 90% by weight of the particles of the active coating material have a particle size in the range of from 1 to 45 microns.

161. (Amended). [A] The method according to claim 156, wherein 90% by weight of the particles have a size less than 70 microns, 50% by weight have a size less than 40 microns and 10% by weight have a size less than 10 microns.

163. (Amended). [A] The method according to claim 162, wherein after the active coating layer is applied the active coating material is fused to form an active film coating on the surface of the substrate.

164. (Amended). [A] The method according to claim 162, wherein active coating material is applied to a plurality of individual regions on the surface of the substrate.

165. (Amended). [A] The method according to claim 164, wherein the amount of active coating material deposited on a given area of the substrate is

controlled such that the product can subsequently be divided into portions with each portion containing a pre-determined amount of active coating material, each pre-determined amount being one dose of the active material.

166 (Amended). A method of coating a substrate using a coating apparatus, the method including the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating is removed as a wafer and divided into smaller portions.

167 (Amended). A method of coating a substrate using a coating apparatus, the method comprising the steps of applying an active coating material to the substrate to form an active coating layer, said substrate being a surface of the coating apparatus, the active coating material comprising biologically active material, wherein the active coating layer is removable from the substrate, and the active coating material is applied electrostatically as a powder, and wherein [the active material is applied to a surface of the coating apparatus and] the active coating is removed as a wafer and divided into smaller portions.

168. (Amended). [A] The method according to claim 167, wherein after

the active coating layer is applied the active coating material is fused to form an active film coating on the surface of the substrate.

170. (Amended). [A] The method according to claim 169, wherein after the active coating layer is applied the active coating material is fused to form an active film coating on the surface of the substrate.

172. (Amended). [A] The coated substrate according to claim 171, wherein the active coating layer is a fused film layer.

173. (Amended). [A] The coated substrate according to claim 171, the substrate further including a cover coating layer on a surface of the substrate, the cover coating layer substantially completely covering the active coating layer wherein the cover coating layer is removable from the substrate together with the active coating layer or separately.

174. (Amended). [A] The coated substrate according to claim 173, wherein the cover coating layer is a fused film layer which has been applied electrostatically as a powder and fused.

175. (Amended). [A] The coated substrate according to claim 173, wherein the cover coating layer includes biologically active material.

176. (Amended). [A] The coated substrate according to claim 171, wherein the quantity of biologically active material on the substrate is substantially equal to one dose of the biologically active material.

177. (Amended). [A] The coated substrate according to claim 171, wherein the active coating layer removed from the substrate constitutes a solid dosage form.

178. (Amended). [A] The coated substrate according to claim 171, wherein the active coating layer comprises

i) a continuous phase component

ii) the biologically active material

iii) a charge-modifying component and

iv) a flow aid.

180. (Amended). [A] The intermediate product according to claim 179, wherein the active coating is fused.

181 (Amended). A intermediate product for use in producing a plurality of solid dosage forms, the intermediate product comprising a substrate and active coating comprising biologically active material in a plurality of regions on

the substrate, the active coating regions being removable from the surface of the substrate, wherein each active coating region includes a cover coating region comprising a layer of cover coating material, each active coating region being substantially completely covered by a cover coating region and [such that] wherein each region of active coating and cover coating is removable from the surface of the substrate, wherein the active coating has been applied electrostatically as a powder.

183 (Amended). An intermediate product [according to claim 181] for use in producing a plurality of solid dosage forms, the intermediate product comprising a substrate and active coating comprising biologically active material in a plurality of regions on the substrate, the active coating regions being removable from the surface of the substrate, wherein each active coating region includes a cover coating region comprising a layer of cover coating material, each active coating region being substantially completely covered by a cover coating region and wherein each region of active coating and cover coating is removable from the surface of the substrate, wherein the active coating layer comprises:

i) a continuous phase component;

ii) the biologically active material;

iii) a charge-modifying component; and

iv) a flow aid.

185 (Amended). [An] The intermediate product according to claim 184, wherein the active coating material is fused.

186 (Amended). [An] The intermediate product according to claim 184, which is a three-layer wafer comprising an active material layer sandwiched between two non-active layers.